

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, IHHS.

ACTION: Notice.

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This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 13, 2002, from 8 a.m. to 5:30 p.m., and on June 14, 2000, from 8 a.m. to 1:30 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 13, 2002, the following committee updates are tentatively scheduled: (1) End user notification, and (2) human immunodeficiency virus (HIV) rapid tests. The committee will hear an informational presentation on the shortage of western blot tests for HIV and electronic submission of biological license applications (BLAs), and discuss and provide recommendations on standards for recovered plasma. In the afternoon, the committee will hear presentations, discuss, and make recommendations on the uniform donor history questionnaire. On June 14, 2002, the following committee updates are tentatively scheduled: (1) Summaries of FDA/Plasma Protein

Therapeutic Association workshop on comparability of plasma derivatives, and (2) the American Association of Blood Bank conference on oxygen therapeutics. The committee will hear an informational presentation on premarket submissions: In-vitro diagnostic software and instruments. The committee will hear presentations, discuss, and make recommendations on the warning label for hetastarch and bleeding.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 3, 2002. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m. and between approximately 4 p.m. and 4:30 p.m. on June 13, 2002; and between approximately 12 noon and 12:30 p.m. on June 14, 2002. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 3, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

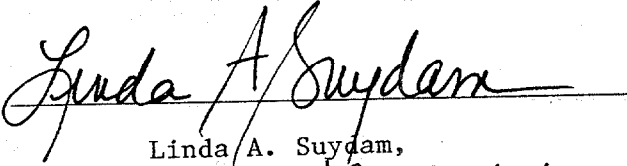
FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Linda A. Smallwood or Pearline K. Muckelvene at 301-827-1281 at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the June 13 and 14, 2002, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 5/23/02
May 23, 2002.



Linda A. Suydam,
Senior Associate Commissioner for Communications and Constituent Relations.

LB
5-23-02

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